Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University
SESSION: STEERING COMMITTEE PANEL

Session Information	**Date: May 31, 2007** **Time: 8:45 a.m.–9:30 a.m. PDT** **Presenter/Lead: John Speakman, Meg Gronvall** **Scribe: Susan Varghese**
Executive Summary	The roles and responsibilities of the Steering Committee were discussed and clarified. The general communication path for the different groups involved in the Workspace, including the Steering Committee, National Cancer Institute Center for Bioinformatics (NCICB), General Contractor (Booz Allen Hamilton), Special Interest Groups (SIG), Task Forces (TF), and Project Execution Teams (PET) were addressed. The Steering Committee members are representatives from the cancer research community and it was recommended that the community reach out to the Steering Committee with feedback, issues, or concerns.
Discussion	• Steering Committee members include— – Bob Annechiarico (Duke University) – Sharon Elcombe (Mayo Clinic) – Charles Hurmiz (St. Jude's) – Kim Johnson (Cancer and Leukemia Group B) – Warren Kibbe, Ph.D. (Northwestern University) – Sorena Nadaf (Vanderbilt University) – Peter Schad, Ph.D. (Federal Observer, NCI Division of Cancer Control and Population Sciences) • The Steering Committee members include 15 clinical trialists, 13 informaticists, 2 patient advocates, and 14 federal observers. The members represent various community centers, including COOPs, Cancer Centers, Community Clinical Oncology Program (CCOP), and Specialized Programs of Research Excellence (SPORE), and have a rich diversity of experience in clinical trials and informatics. • The process by which the Steering Committee was selected involved requesting input from more than 200 thought leaders, including Cancer Center directors, Cooperative Group chairs, CCOP and SPORE PIs. The response was more than sufficient to ensure that a broad representation of clinical trial experts and informaticists were selected. • The remit of the Steering Committee is to provide strategic guidance and direction to the General Contractor, Booz Allen Hamilton, in the management of clinical trials activities within the Workspace. • The Steering Committee's role is to guide caBIG™ General Contractor on the strategic direction of the NCI's informatics work in support of clinical trials. The NCI's role is to implement this strategic direction with tactical decisions and policies. The Steering Committee does not have the power to make budget decisions, so in that sense it can be "overridden" by the Government. However, these decisions are tactical rather than strategic. • The role of the Federal Observers is to observe the activities of the Steering Committee and provide governmental perspectives and input on matters of fact. • The Steering Committee panel, NCICB, and Booz Allen addressed the following questions from the attendees: Q: How are Steering Committee decisions governed?

A: The Steering Committee provides guidance to Booz Allen Hamilton, which is the General Contractor designated by NCICB. Booz Allen, in consultation with NCICB, will provide input to the SIGs, TFs, and PETs, who in turn will report to Booz Allen. The TFs will also report to the Steering Committee periodically on the activities in which they are engaged. The Steering Committee will meet quarterly; its members may also self-select into the four clinical trial focus areas, namely, planning/monitoring, study conduct, reporting/sharing, and interoperability.

Q: The responsibilities of the Steering Committee seems rather diffuse, could you make it clearer?

A: The Steering Committee's role will be to provide guidance and strategic direction to Booz Allen. All decisions pertaining to the CTMS activities will be made by NCI. NCI will receive, and take into account, feedback, input, and suggestions from the Steering Committee via Booz Allen, just as it receives such feedback from the SIGs, the Workspace, and the larger community.

Q: It would be helpful to have the activities of the Steering Committee as transparent as possible. Are there ways in which caBIG™ leadership can facilitate this?

A: The meeting is publicized on the caBIG™ website, and the meeting notes are also posted to the website. The Steering Committee activities have to broadly integrate with the community and vice-versa. It is anticipated that the Steering Committee Panel will continue to be a feature of face-to-face meetings henceforth. NCI will continue to explore ways to publicize the work of the Steering Committee and to solicit community input and feedback—suggestions are welcomed.

Q: Establishing the Steering Committee is a step in the right direction, but what steps are being taken to involve the clinical trialists, such as CRAs, PIs, etc.?

A: This is reflected in the composition of the Steering Committee, in that one-third of the members are clinical trialists. They represent clinical trialists in the community and will bring to the surface issues, concerns, and recommendations from the community. Research Nurses and CRAs currently participate in the SIGs but we need to broaden their involvement. We will also need to ensure that we enlist clinical trialists from Cooperative Groups; NCI will continue to seek ways in which to achieve this.

Q: What is the communication path from workspace members to the Steering Committee?

A: There are a variety of paths, and Workspace members should use the path with which they feel most comfortable. The Steering Committee is part of the larger community and so the SIG members should feel free to communicate with them directly; also, Booz Allen and NCICB are happy to facilitate this communication. Again, further suggestions are welcomed.

Q: What are the roles of the TFs and the SIGs?

A: There will be a TF for each SIG. TFs are responsible for setting the tactical direction of the projects in each SIG, including prioritization of the SIG projects and activities. The SIGs are members of the community who are interested in vetting project artifacts (documents, software, etc.) and providing input and feedback on functionality, usability, applicability, etc. Each TF will coordinate and meet with the SIG and its PETs regularly.

Q: How will interoperability projects be prioritized across SIGs?

A: The Interoperability SIG and the Clinical Trials Management System Interoperability (CTMSi) Project Team will be responsible for driving interoperability among the CTMS application development projects, ensuring consistency in terms of common look-and-feel, enforcing architectural governance, and influencing functional prioritization. These decisions will be informed by subject matter experts (SME) on the Interoperability TF and the CTMSi Project Team, working collaboratively with their counterparts on each of the PETs.

Q: All clinical trials start with the protocol defining data elements and study structure. Are there activities focused on this?

A: Yes. The Structured Protocol Representation SIG focused on this aspect and is the predecessor to the Biomedical Research Integrated Domain Group (BRIDG) model. BRIDG is one of the projects under the Interoperability SIG. It is a developing domain analysis model that is focused on protocol-driven research. All PETs in the CTMS Workspace begin their development activities using the BRIDG model and extend it if necessary. The purpose of using BRIDG as a starting point is to support semantic interoperability among the CTMS modules.